(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 September 2004 (16.09.2004)

PCT

(10) International Publication Number
WO 2004/078246 A1

(51) International Patent Classification[7]: A61M 16/00

(21) International Application Number:
PCT/AU2004/000272

(22) International Filing Date: 5 March 2004 (05.03.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2003901042 7 March 2003 (07.03.2003) AU

(71) Applicant *(for all designated States except US)*: **RESMED LIMITED** [AU/AU]; 97 Waterloo Rd, North Ryde, NSW 2113 (AU).

(72) Inventor; and

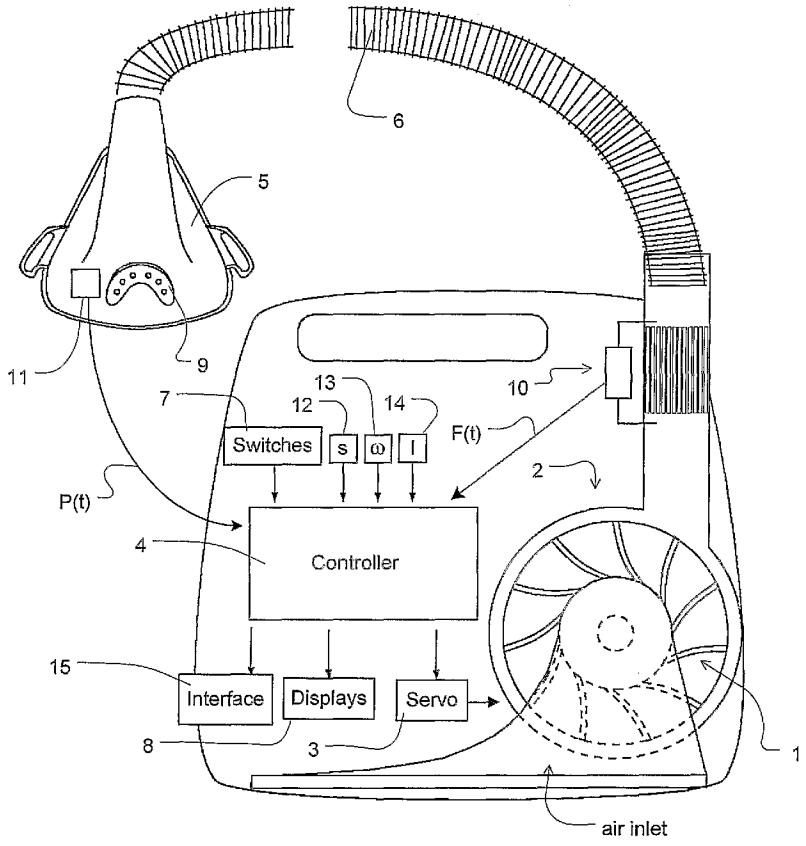
(75) Inventor/Applicant *(for US only)*: **BASSIN, David, John** [AU/AU]; 52 Dolphin St, Coogee, NSW 2034 (AU).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: METHODS AND APPARATUS FOR VARYING THE BACK-UP RATE FOR A VENTILATOR



(57) Abstract: A ventilator device delivers ventilatory support to a patient in a back up timed mode (22) when patient respiration is not detected or a spontaneous mode when patient respiration is detected (20). The timing threshold (18) governing the back-up mode is chosen to deviate from normal expected respiration time for the patient to promote patient initiated ventilation in the spontaneous mode but permit back-up ventilation in the event of apnea. Automated adjustments (28, 30) to the timing threshold during the timed mode are made from the less vigilant timing threshold to a more vigilant threshold at or near a timing of normal expected breathing of the patient. Such adjustments may be made from a minimum to a maximum vigilance timing settings or incrementally there between as a function of time in the timed mode which is preferably the number of delivered machine breaths.

WO 2004/078246 A1

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

METHODS AND APPARATUS FOR VARYING THE BACK-UP RATE FOR A VENTILATOR

This application claims the benefit of Australian provisional patent application no. 2003901042, filed on March 7, 2003.

Field of the Invention

The invention relates to the field of automatically controlled mechanical ventilators for use in treating respiratory disorders such as respiratory insufficiency. In particular, the invention relates to a method and apparatus providing a more appropriate back-up rate for ventilation when patients are not breathing spontaneously.

Background of the Invention

Both positive and negative pressure mechanical ventilators have been used for decades to treat patients with respiratory disorders. A range of ventilators are described in "Principles & Practice of Mechanical Ventilation", Edited by MJ Tobin (1994, McGrawHill Book Company, ISBN 0-07-064943-X). Other ventilators are described in "Respiratory Therapy Equipment", by S.P. McPherson (3rd Ed., 1985, C.V. Mosby Company, ISBN 0-8016-3312-5). Other ventilators are described in "Automatic Ventilation of the Lungs" by Mushin et al (3rd Ed, 1980, Blackwell Scientific Publications, ISBN 0-632-002286-7).

Positive pressure ventilators provide a supply of air or breathable gas at positive pressure to a patient's airway. Flow is volume of air per unit time. Tidal volume is the volume of air entering and leaving the lungs during the respiratory cycle. Minute ventilation is the volume of air delivered to a patient in 1 minute. There are two general approaches to control of ventilators: (1) volume or flow; and (2) pressure control. A ventilator may be programmed to control the volume of air delivered to a patient by adjusting the minute ventilation. The rate at which the air is delivered to the patient is breaths (or cycles) per unit time.

In order to achieve the desired minute ventilation, both the rate and volume of air delivered to a patient can be varied.

In this specification, a ventilator will be said to be *triggered* into an inspiratory phase and *cycled* into an expiratory phase. *Spontaneous* breaths are those that are initiated by the patient. If the ventilator determines either the start or end of inspiration, then the breath is considered *mandatory*. If the patient triggers the ventilator (e.g., with a

spontaneous breath), the ventilator is said to be an *assistor*. If time triggers the ventilator into the inspiratory phase, the ventilator is said to be a controller. If the patient can assist and the machine can back him up (if his breathing rate drops or stops altogether), the ventilator is designated an assistor/controller. It is possible for a machine to be all three. It is:

(1) an assistor when it is patient-triggered and there is no timed backup rate;

(2) a controller when it is time-triggered and no assist mechanism is provided; or

(3) an assistor/controller when the timed rate backs up the patient's rate (sometimes called "spontaneous/timed").

When the ventilator switches between inspiratory and expiratory modes at the same time as the spontaneously breathing patient, the ventilator is said to be in synchrony with the patient. Loss of synchrony can lead to patient discomfort and ineffective ventilation. For purposes of this description, a spontaneous/timed ventilator is considered to be in a spontaneous mode when it is delivering ventilation support in response to detected patient respiration. Similarly, the spontaneous/timed ventilator is considered to be in a timed mode when it is delivering a machine breath according to a back up timing threshold back up rate in response to a failure to detect patient respiration.

A method for providing ventilatory assistance in a spontaneously breathing subject is described in US Patent 6,484,719 (Berthon-Jones), the contents of which are hereby incorporated by cross-reference.

In some situations, a spontaneous/timed ventilator can fail to detect when the patient switches between inspiration and expiration. Therefore some ventilators have a "time-out" for a spontaneous mode. Such ventilators will switch from the spontaneous mode (waiting for the patient) to a timed mode (delivering ventilation at the back up rate) at the end of the time-out period. An improved system for a "time-out" is described in US Patent 6,213,119, the contents of which are hereby incorporated by cross-reference.

As discussed herein, the back-up rate (cycles/time) may be alternatively described by its reciprocal, the back-up period (time/cycle).

In programming an automatic ventilator, the problem arises as to the choice of the most appropriate back-up rate for the device.

Summary of the Invention

In accordance with a first aspect of the invention, a ventilator is designed with a back-up process or back up timing module such that it is configured or programmed to deliver timed breaths with a timing threshold or back-up rate in the event a spontaneous

breath is not detected. The timing threshold or back up rate may, in a first embodiment, be set to a first rate that is substantially lower (i.e., less frequent) than the patient's normal respiratory rate. In this regard it is chosen to depart or deviate from that which would ordinarily be associated with normal or expected patient respiration in a manner that promotes patient initiated ventilation by the ventilator but allows timed ventilation in the event of apnea. Accordingly, the first rate is set substantially lower so that the ventilator will less likely interfere with the patient's normal breathing cycle, meaning that the chances for the ventilator to resume a spontaneous mode from a timed mode or continue within spontaneous mode are increased when the instantaneous backup rate is lower than the backup rate which would have been set with a conventional fixed backup rate ventilator. In other words, if the patient again commences spontaneous breathing, the timed mode is discontinued or the spontaneous breathing mode continues. If the patient continues to require timed ventilation in the absence of detected breathing, meaning that spontaneous breathing has not re-commenced, the ventilator will automatically normalize the timing threshold to a more vigilant timing or an approximately normal expected respiratory timing. Thus, the ventilator gradually or step-wise increases the breathing rate from the first rate to a second rate which is at, closer to, or slightly lower than the patient's normal breathing rate. Of course, the second rate may also change to be higher than the patient's normal breathing rate, depending on the particular application.

In other words, a low timed rate is used to decrease the likelihood of false entry into the timed mode of the ventilator yet the timing rate is adjustable in the timed mode to permit appropriate ventilation of a patient during the timed mode. Thus, the back-up rate is automatically adjusted as a function of elapsed time in the timed mode, increasing towards the patient usual or average respiratory rate. In terms of a timing threshold that is a back-up period, the back-up period is automatically adjusted as a function of the time in the timed mode, decreasing towards the patient's usual or average respiratory period.

In another aspect, the timed rate may be adjustable between two limits, namely, a first lower rate and a second rate, higher than the first. In one form, the first rate is significantly lower than the patient's usual respiratory rate and the second rate is at or slightly lower than the patient's usual respiratory rate. Of course, the second higher rate may optionally be at or higher than the patient's usual or average respiratory rate. When the ventilator switches to the timed mode, having failed to detect a spontaneous breath, the ventilator is initially set to the first lower rate and then the patient is ventilated. If after a predetermined period, a spontaneous patient breath still has not been detected by the

ventilator, the back-up rate is increased towards the second rate. In one preferred form, apparatus in accordance with the invention changes the back-up rate from the lower rate to the faster rate over approximately 5 breaths within the timed mode if spontaneous breaths are not detected.

In one form, in apparatus in accordance with the invention, the second rate is approximately 25% faster than the first rate. In another preferred form, the second rate is approximately 50% faster than the first rate.

In another embodiment, the adjustable back-up rate is automatically modified as a function of adequacy of ventilation. In a preferred embodiment of such an adjusting back-up rate, ventilation adequacy affects the rate of change of the adjustments to the back-up rate between its minimum and maximum values.

In one embodiment, within the timed mode the device periodically returns the timing threshold to a less vigilant timing threshold to promote resynchronization with the patient.

Other aspects of the invention are described in the detailed description herein.

Brief Description of the Drawings

Fig. 1 shows a ventilator programmed in accordance with an embodiment of the invention;

Fig. 2 is a flow chart of one embodiment of steps taken in the automatic adjustment of a timing threshold;

Fig. 3 is a flow chart of an alternative embodiment of steps taken in the automatic adjustment of a timing threshold;

Fig. 4 shows a "delta" function for adjusting the back-up rate in accordance with the adequacy of ventilation.

Detailed Description of Preferred Embodiments

Fig. 1 shows, by way of example, apparatus suitable for performing the invention. Fig. 1 shows an impeller 1 connected to an electric motor 2 under the control of a servo-controller 3 which is in turn under the control of a controller 4. In one form the controller 4 is a micro-processor based controller, such as an Intel '486 microprocessor. The impeller 1 and motor 2 form a blower. Air from the blower passes along a flexible conduit 6 to a patient interface such as a nasal mask 5 with a vent 9. While a nasal mask is illustrated, the invention may be used in conjunction with a nose-and-mouth mask, full face mask or endo-tracheal tube. A number of switches 7 are connected to the controller. A number of sensors are connected to the controller, namely: flow 10, pressure 11, snore 12, motor

speed 13 and motor current 14. There are a set of displays 8 connected to the controller 4 for displaying information from the controller. There is an interface 15 to enable the controller 4 to communicate with an external device such as a computer. With such a device, changes in the speed of the blower may be controlled to alternatively change the pressure in the mask to implement ventilatory support. Optionally, the blower motor speed may be held generally constant and pressure changes in the mask may be implemented by controlling an opening of a servo-valve (not shown) that may variably divert/vent or deliver airflow to the mask. Those skilled in the art will recognize other devices for generating ventilatory support and delivering same to a patient.

The controller 4 or processor is configured and adapted to implement the methodology described herein and may include integrated chips, a memory and/or other instruction or data storage medium. For example, programmed instructions with the control methodology may be coded on integrated chips in the memory of the device or such instructions may be loaded as software. With such a controller, the apparatus can be used for many different pressure ventilation therapies simply by adjusting the pressure delivery equation that is used to set the speed of the blower or to manipulate the venting with the release valve. Those skilled in the art will also recognize that aspects of the controller may also be implemented by analog devices or other electrical circuits.

Generally speaking, as illustrated by the step of the flowchart of Fig. 2, a device in accordance with the invention can deliver ventilatory support in a spontaneous mode (step 22) to synchronously ventilate the patient in accordance with detecting the patient's inspiration (step 20). However, if the patient inspiration is not detected before the lapsing of some timing threshold (e.g., a timing rate ($1/T_{current}$) or timing period ($T_{current}$)) determined by comparison of the threshold by a measured rate or period (step 24), the device will initiate a timed mode (step 26) in which a machine initiated breath will be delivered. Those skilled in the art will recognize methods for entering the timed mode by enforcing a timing threshold. Automated adjustments to the timing threshold, ($1/T_{current}$ or $T_{current}$) may then be implemented in steps 28 and 30 as described further herein.

In the following description, "period" means the reciprocal of rate unless otherwise indicated. Define T_{apn} to be a desired time for the backup period while the patient is not breathing or the desired time from the start of an inspiratory breath (non-patient triggered) to the time for the start of a subsequent inspiratory breath (non-patient triggered), namely the reciprocal of the rate desired when the patient is not triggering the ventilator and is at least apparently, if not actually apnoeic, from the point of view of the ventilator. Preferably

this rate is approximately that of the normal expected respiratory rate for the patient but it may be higher or lower as desired. Define T_{spont} to be the desired time for the backup period while the patient is spontaneously breathing which is preferably chosen to deviate from the normal expected respiratory rate of the patient such that the timing threshold is less vigilant than normal breathing. Define $T_{current}$ to be a current backup period being applied to control the delivery of ventilation to the patient.

If the current breath started at time $t_{breathstart}$ then a machine initiated or "timed" breath will occur at $t_{breathstart} + T_{current}$ if the patient has not triggered the ventilator before this time. It is to be understood that T_{spont} and T_{apn} are chosen so that with the respiratory mechanics of the Patient being treated, a decrease in respiratory period from T_{spont} to T_{apn}, with fixed pressure support levels, results in a monotonic increase in ventilation. Those skilled in the art will recognize various methods for determining the time of recurring respiratory event $t_{breathstart}$. or otherwise detecting an event in the respiratory cycle for purposes of timing the delivery of spontaneous or timed cyclical ventilation support.

(I) Basic Methodology

$T_{current}$ is initialized to T_{spont}. If a timed breath occurs, $T_{current}$ is decremented by some amount $\Delta_d T_{current}$ (not necessarily a constant) and the result is then limited to be at least T_{apn}. More specifically, in one implementation, $T_{current}$ is decremented by $(T_{spont} - T_{apn})/N_{dec}$, where N_{dec} is, for example, 5, so that in this case after 5 timed breaths the apnoeic backup rate is reached. This adjustment to the timing threshold is illustrated in step 28 of Fig. 2.

Generally N_{dec} should not be too small (e.g., 1) because one wants to maximize the chances of resynchronising with the patient. The longer the period of time during which the patient has not triggered the ventilator, the less likely it is that triggering will occur in the immediate future, and the more likely it is that hypoxia will occur if timed ventilation continues at a low rate.

If a triggered breath occurs at any time, $T_{current}$ is incremented by some amount $\Delta_i T_{current}$, and the result is then limited so that it is at most T_{spont}. More specifically, in one implementation, $T_{current}$ is incremented by $(T_{spont} - T_{apn}) / N_{inc}$, where in the preferred implementation $N_{inc} = 1$, so that in this case after 1 triggered breath the backup rate returns immediately to the spontaneous breathing backup rate T_{spont}. It is desirable that $N_{inc} < N_{dec}$, because if one spontaneous breath is detected there are likely to be more, and one wants to maximize the chance of triggering on the next one. This adjustment to the timing threshold is illustrated in step 30 of Fig. 2.

In one implementation as illustrated by Fig 3, when successive timed breaths are delivered with a period of T_{apn} occasional breaths (for example, 1 breath in each contiguous series of 10 timed breaths) are delivered with a longer period, up to T_{spont} in order to increase the chance of resynchronizing with the patient, while on average ventilating the patient at a rate close to the reciprocal of T_{apn}. Thus, while the ventilator is in the timed mode, the back-up rate may be periodically modified or relaxed to be less vigilant for the purpose of promoting resynchronization with the patient as illustrated in step 34 of Fig. 3 if a certain number of consecutive timed breaths occur (step 32). Thus, in the timed mode the rate or period may be decreased or increased respectively for a breath cycle. For the following breath cycle the back-up rate is returned to a more vigilant rate or period (e.g., the patient normal expected or average breath rate or period) if no patient breath is detected that would trigger the spontaneous mode as a result of the more relaxed back-up rate or period. For example, in step 30 the ventilator may return $T_{current}$ to T_{spont} and then repeat the methodology above for increasing back toward T_{apn} or as preferred, after a single machine generated breath, the ventilator will adjust $T_{current}$ back to T_{apn} in step 28.

(II) Advantages

Advantages of the invention include the ability to set a lower backup rate than usual, so as to interfere less than usual with the patient's spontaneous breathing, while setting a higher and thus more efficient rate which will prevail when the patient is genuinely or effectively apnoeic, thus allowing lower pressure support levels.

(III) Algorithm Using Measured Ventilation to Modify Back-Up Rate Variation Speed

If a rapidly-responding measure of minute ventilation is available (with a response time typically of the order of 2 or 3 breaths, e.g., a 4^{th} order Bessel lowpass filter of the absolute value of flow with a corner frequency of about 3.2/60 Hz), and there is also available a desired or target ventilation (as in a servoventilator, the typical case envisaged here, though the ventilator need not actually be servo-controlling the ventilation--some advantages still accrue without servo-control), then $\Delta_d T_{current}$ can be made to depend on some measure of the adequacy of the actual ventilation, for example, the ratio R_{vent} of the measured ventilation to the target ventilation (e.g., V_{meas}/V_{targ}) which may be determined from a signal from a flow sensor or differential pressure transducer configured to do so. When R_{vent} is significantly larger than 1, say ≥ 1.2, then $\Delta_d T_{current}$ can be chosen to be 0, because ventilation is entirely adequate. In the case of a servoventilator with a low or

zero minimum pressure support level, if all breaths are timed, R_{vent} cannot stay at ≥ 1.2 for any significant period of time, because the fact that R_{vent} is more than 1 will cause the pressure support level to be reduced so that $R_{vent} \approx 1$. The situation of a timed breath occurring with R_{vent} being ≥ 1.2 may typically occur when a sigh is followed by a brief pause, and it is not desirable to decrement $T_{current}$ under these circumstances, because a spontaneous breath will probably occur very soon, and one wants to maximize the chances of synchronizing with it. In the absence of servo-control of pressure support level, R_{vent} being ≥ 1.2 indicates that more than adequate ventilation is being achieved at a low rate at the set pressure level (presumably regarded as acceptable), so there is no need to increase the rate.

When R_{vent} is significantly less than 1, $\Delta_d T_{current}$ can be increased, so that, for example, if there is marked hypoventilation, $T_{current}$ may decrease from T_{spont} to T_{apn} in 2 breaths, because in this situation it is desirable to get to the more efficient apnoeic backup rate quite rapidly. Intermediate values of R_{vent} should produce intermediate values of $T_{current}$ in a monotonic fashion but not necessarily using linear interpolation between the endpoints (i.e., T_{spont} and T_{apn}). To derive the full benefit of this invention in the case of a servoventilator, it is essential that $\Delta_d T_{current} > 0$ when $R_{vent} \approx 1$. The reason for this is that the automatic increase in pressure support in response to the fact that when $R_{vent} < 1$ it may rapidly cause the hypoventilation to be corrected, i.e. $R_{vent} \approx 1$, so that if $\Delta_d T_{current} \approx 0$ when $R_{vent} \approx 1$, the backup period may never decrease, resulting in sustained ventilation of the patient at a lower than optimal rate using higher than optimal pressure. To prevent this, it is desirable that when $R_{vent} \approx 1$, $\Delta_d T_{current} \geq (T_{spont} - T_{apn})/10$.

Fig. 3 illustrates a piecewise linear "delta" function for adjusting the back-up rate in accordance with the adequacy of ventilation by the following formula:

$$\Delta_d T_{current} = (T_{spont} - T_{apn}) * K_{dec}(R_{vent})$$

As depicted in the figure, the x-axis shows a measure of the adequacy of ventilation R_{vent}. The y-axis shows the relative size of a correction factor (K_{dec}) to be applied to the back-up rate. For example, a value of 0.2 on the x-axis indicates a low adequacy of ventilation which is compensated by a relatively high correction factor, causing the back-up rate to be increased by a larger delta. In other embodiments of the invention, the delta function may have different shapes, e.g., linear, curved and/or combinations thereof. The delta function may also have other input parameters.

It should be noted that the combination of this algorithm with a fixed pressure level constitutes a form of servo-control of ventilation during apnea, though this is not the

primary intention of this invention. Such a servo-control algorithm based on rate would require $\Delta_d T_{current}$ to be negative when the ventilation is above target.

In one form the apparatus has a learning mode as described in published Australian patent application AU 24896/01 (Berthon-Jones) entitled "Determining Suitable Ventilator Settings in Patients with Alveolar Hypoventilation During Sleep", also disclosed in U.S. Patent no. 6,644312, the disclosure of which is incorporated by reference. During the learning mode, the device learns the patient's natural breathing rate. The lower back-up rate is then set as a function of the rate, preferably at approximately 2/3 or 67%, or alternatively 75%, of that rate, and the higher rate is set at the rate determined to be the patient's natural breathing rate or the average normal breathing rate determined from a period of time. Of course, the ventilator may include a function to prompt for input by a user of the higher and/or lower respiratory rates or periods as desired or necessary.

In one form the back-up rate is changed from the first rate to the second rate in a stepwise manner, by adding a "delta" to the back-up rate. The delta may be of fixed size, or it may be a function of a measure of the adequacy of the ventilation. In the following example of one embodiment of the invention, implemented in the C++ programming language, the function determining the size of a delta function is illustrated:

```
int VPAP _ST _Sync_RelVentErrT::CalcBackupPeriodDecrement()
{
  // Return decrement in ticks at HZ.

  int MaxBackupDecrement = BackupPeriodWhenBreathing - BackupPeriodApnoeic;
  double RelVentErr;
  if (RelativeVentilationErrGetP = NIL ||
      ! RelativeVentilationErrGetP->Get ( RelVentErr )
     )
// No information available about ventilation error.
return MaxBackupDecrement /5;

// A goal is that if the ventilator is providing timed breaths and Is
// just reaching the target ventilation, we want to ensure that the
// apnoeic rate is reached reasonably quickly. We don't want to get
// stuck providing high pressure support at a low rate and meeting
// target this way.

if ( RelVentErr >= 0.3 )
// Well over target, so don't change backup period at all. This might
// be e.g. a pause after a sigh.
  return 0;

double PropnOfMaxDecrement;
```

```
if (RelVent Err >= -0.1)
  PropnOfMaxDecrement = 0.2*(0.3 - RelVentErr)/0.4;
else
 {
  if (RelVentEff < -1.0)
    RelVentErr = -1.0; // should be unnecessary

  PropnOfMaxDecrement = (-0.1 - RelVentErr) / 0.9;
 }

return (int) (PropnOfMaxDecrement * MaxBackupDecrement + 0.5);
}
```

Although the invention has been described with reference to preferred embodiments, it is to be understood that these embodiments are merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention.

Claims,

1. A method for setting back up support ventilation for a patient comprising the steps of:

delivering pressure support ventilation to a patient during inspiratory and expiratory portions of a breathing cycle of the patient;

detecting a recurrent respiratory event in a cycle of the patient's respiration;

setting a timing threshold for controlling the delivery of pressure support ventilation subsequent to the recurrent respiratory event and in an absence of a detection of a subsequent recurrent respiratory event;

controlling a delivery of pressure support according to the timing threshold in the absence of a detection of a recurrent respiratory event subsequent to a detected recurrent respiratory event;

wherein the step of setting a timing threshold, said timing threshold is chosen to deviate from a normal expected respiration timing for the patient in a manner that promotes patient initiated synchronization of the pressure support ventilation but permits back-up ventilation in the event of an apnea.

2. The method of claim 1 further comprising the step of automatically adjusting the timing threshold in the absence of a detection of a subsequent recurrent respiratory event to normalize the timing threshold toward an expected normal respiration timing for the patient.

3. The method of claim 2 wherein the timing threshold adjusts stepwise as a function of a number of delivered cycles of ventilation delivered in response to the timing threshold.

4. The method of claim 2 further comprising the step of automatically adjusting the timing threshold in the presence of a detection of a subsequent recurrent respiratory event to adjust the timing threshold towards a timing threshold chosen to deviate from a normal expected respiration timing for the patient.

5. The method of claim 4 wherein the timing threshold adjusts stepwise as a function of a number of delivered cycles of ventilation delivered in response to detected patient respiration.

6. The method of claim 5 wherein in response to a detection of a single respiratory cycle by the patient, the timing threshold returns to an original timing threshold chosen to deviate from a normal expected respiration timing for the patient.

7. The method of claim 6 wherein the timing threshold is a respiratory rate, and in the step of automatically adjusting the timing threshold in the absence of a detection of a subsequent recurrent respiratory event, said respiratory rate increases from a rate chosen to deviate from a normal expected respiration rate for the patient toward a normal expected respiration rate.

8. The method of claim 7 wherein automated adjustments to the timing threshold are restricted by a maximum respiratory rate that is about 50 percent faster than the rate chosen to deviate from a normal expected respiration rate.

9. The method of claim 7 wherein automated adjustments to the timing threshold are restricted by a minimum respiratory rate that is calculated as a fraction of a normal respiratory rate determined during a learning period.

10. The method of claim 9 wherein the fraction is about 67%.

11. The method of claim 6 wherein the timing threshold is a respiratory period, and in the step of automatically adjusting the timing threshold in the absence of a detection of a subsequent recurrent respiratory event, said respiratory period decreases from a period chosen to deviate from a normal expected respiration period for the patient toward a normal expected respiration period.

12. The method of claim 2 further comprising the step of determining adequacy of the patient's ventilation and wherein automated adjustments to the timing threshold are a function of the adequacy of the patient's ventilation.

13. The method of claim 12 wherein the function of the adequacy of the patient's ventilation includes a ratio of a measured ventilation and a target ventilation.

14. The method of claim 13 wherein the measured ventilation is a minute ventilation and the function is piecewise linear on a ratio of a measured minute ventilation to a target minute ventilation.

15. The method of claim 2 further comprising the step of automatically periodically returning the normalized timing threshold to the timing threshold chosen to deviate from a normal expected respiration in the absence of a detection of a subsequent recurrent respiratory event.

16. The method of claim 15 further comprising the step of changing the timing threshold back towards the normalized timing threshold after delivering a machine breath if a subsequent recurrent respiratory event remains undetected during application of the the timing threshold chosen to deviate from a normal expected respiration.

17. The method of claim 16 wherein the periodic return occurs as a function of a number of delivered machine breaths.

18. An apparatus for providing back up ventilation to a patient comprising:

a ventilator adapted to generate and deliver ventilatory support to a patient; and

a controller configured to control the ventilatory support provided by the ventilator,

wherein the controller is configured with a spontaneous mode in which synchronized cyclical ventilatory support is initiated by detecting the presence of a respiratory cycle of the patient;

wherein the controller is further configured with a timed mode in which cyclical ventilatory support is delivered in accordance with a timing threshold in the absence of detecting a respiratory cycle of the patient, and

wherein the controller is configured to set the timing threshold as a function of normal expected respiratory timing for the patient, said function chosen to deviate the timing threshold from the normal expected respiration timing for the patient in a manner that promotes patient initiated synchronization of the ventilatory support but permits back-up ventilation in the event of an apnea.

19. The apparatus of claim 18 wherein the controller is further configured to automatically adjust the timing threshold in a timed mode in the absence of detecting a respiratory cycle

of the patient from a timing threshold deviating from a normal expected respiration timing for a patient toward a normal expected respiration timing for the patient.

20. The apparatus of claim 19 wherein the timing threshold adjusts stepwise as a function of a number of delivered cycles of ventilation delivered in response to the timing threshold.

21. The apparatus of claim 20 wherein the controller is further configured to automatically change the timing threshold upon the detection of the presence of a respiratory cycle of the patient by adjusting the timing threshold towards a timing threshold deviating from a normal expected respiration timing for the patient.

22. The apparatus of claim 21 wherein the timing threshold adjusts stepwise as a function of a number of delivered cycles of ventilation delivered in response to detected respiratory cycles of the patient.

23. The apparatus of claim 22 wherein in response to a detection of a single respiratory cycle by the patient, the timing threshold returns to an original timing threshold chosen to deviate from a normal expected respiration timing for the patient.

24. The apparatus of claim 19 wherein the timing threshold is a respiratory rate, and the controller in automatically adjusting the timing threshold in the timed mode increases the timing threshold from a minimum rate lower than a normal expected respiration rate for the patient toward a maximum higher rate approximately that of normal expected patient respiration.

25. The apparatus of claim 24 wherein the automated adjustments to the timing threshold are restricted by a maximum respiratory rate that is about 50 percent faster than the minimum rate.

26. The apparatus of claim 24 wherein the minimum respiratory rate is calculated as a fraction of a normal respiratory rate determined during a learning period.

27. The apparatus of claim 26 wherein the fraction is about 67%.

28. The apparatus of claim 18 wherein the function of normal expected respiratory rate for the patient is a fixed percent of a learned respiratory rate for the patient.

29. The apparatus of claim 28 wherein the fixed percent is about 67%.

30. The method of claim 19 wherein the timing threshold is a respiratory period, and the controller in automatically adjusting the timing threshold decreases it from a maximum period deviating from a normal expected respiration period toward a minimum lower period approximately that of normal expected respiration.

31. The apparatus of claim 18 wherein the controller is further configured to determine adequacy of the patient's ventilation and adjust the timing threshold as a function of the adequacy of the patient's ventilation.

32. The apparatus of claim 31 wherein the function of the adequacy of the patient's ventilation includes a ratio of a measured ventilation and a target ventilation.

33. The apparatus of claim 32 wherein the measured ventilation is a minute ventilation and the function of the adequacy of the patient's ventilation is piecewise linear on a ratio of a measured minute ventilation to a target minute ventilation.

34. The apparatus of claim 18 wherein the controller is further configured in the absence of a detection of a respiratory cycle of the patient to automatically periodically return the timing threshold from a more vigilant threshold approximating normal expected respiration timing to a less vigilant threshold deviating from normal expected respiration timing.

35. The apparatus of claim 34 wherein the controller is further configured to change the timing threshold to the more vigilant threshold from the less vigilant timing threshold after delivering a machine breath if a subsequent respiratory cycle of the patient remains undetected during application of the less vigilant timing threshold.

36. The apparatus of claim 34 wherein the controller periodically returns the timing threshold as a function of a number of consecutive delivered machine breaths.

37. An apparatus for providing back up ventilation to a patient comprising:

a patient interface and conduit coupled for delivering a controlled supply of breathable gas to a patient;

a controllable blower device coupled to the conduit to generate the supply of breathable gas, the supply of breathable gas providing ventilatory support for the patient;

a pressure transducer configured to detect a measure of patient respiration through the interface and generate a signal indicative of the measure; and

a processor coupled with the blower device and transducer to control the delivery of the supply of breathable gas to the patient,

wherein the processor includes coded instructions to control a spontaneous mode in which synchronized cyclical ventilatory support is initiated by detecting the presence of a respiratory cycle of the patient from the signal from the pressure transducer;

wherein the controller is further includes coded instructions to control a timed mode in which cyclical ventilatory support is delivered in accordance with a timing threshold in the absence of detecting a respiratory cycle of the patient from the signal from the pressure transducer, and

wherein the processor further includes coded instructions to set the timing threshold as a function of normal expected respiratory timing for the patient, said function chosen to deviate the timing threshold from the normal expected respiration timing for the patient in a manner that promotes patient initiated synchronization of the ventilatory support but permits back-up ventilation in the event of an apnea.

38. The apparatus of claim 37 wherein the processor further includes coded instructions to automatically adjust the timing threshold in a timed mode in the absence of detecting a respiratory cycle of the patient from a timing threshold deviating from a normal expected respiration timing for a patient toward a normal expected respiration timing for the patient.

39. The apparatus of claim 38 wherein the timing threshold adjusts stepwise as a function of a number of delivered cycles of ventilation delivered in response to the timing threshold.

40. The apparatus of claim 39 wherein the processor further includes coded instructions to automatically change the timing threshold upon the detection of the presence of a respiratory cycle of the patient to adjust the timing threshold towards a timing threshold deviating from a normal expected respiration timing for the patient.

41. The apparatus of claim 40 wherein the timing threshold adjusts stepwise as a function of a number of delivered cycles of ventilation delivered in response to detected respiratory cycles of the patient.

42. The apparatus of claim 41 wherein in response to a detection of a single respiratory cycle by the patient, the timing threshold returns to an original timing threshold chosen to deviate from a normal expected respiration timing for the patient.

43. The apparatus of claim 38 wherein the timing threshold is a respiratory rate, and the coded instructions of the processor control automatically adjusting of the timing threshold in the timed mode to increase the timing threshold from a minimum rate lower than a normal expected respiration rate for the patient toward a maximum higher rate approximately that of normal expected respiration.

44. The apparatus of claim 43 wherein automated adjustments to the timing threshold are restricted by a maximum respiratory rate that is about 50 percent faster than the minimum rate.

45. The apparatus of claim 44 wherein coded instructions of the processor calculate the minimum respiratory rate as a fraction of a normal respiratory rate determined during a learning period.

46. The apparatus of claim 45 wherein the fraction is about 67%.

47. The apparatus of claim 37 wherein the function of normal expected respiratory rate for the patient is a fraction of a learned respiratory rate for the patient.

48. The apparatus of claim 47 wherein the fraction is about 67%.

49. The apparatus of claim 38 wherein the timing threshold is a respiratory period, and the coded instruction of the processor control automatically adjusting the timing threshold by decreases it from a maximum period deviating from a normal expected respiration period toward a minimum lower period approximately that of normal expected respiration.

50. The apparatus of claim 37 wherein the processor further includes coded instructions to determine adequacy of the patient's ventilation from a signal from the pressure transducer and adjust the timing threshold as a function of the determined adequacy of the patient's ventilation.

51. The apparatus of claim 50 wherein the function of the adequacy of the patient's ventilation includes a ratio of a measured ventilation and a target ventilation.

52. The apparatus of claim 51 wherein the measured ventilation is a minute ventilation and the function of the adequacy of the patient's ventilation is piecewise linear on a ratio of a measured minute ventilation to a target minute ventilation.

53. The apparatus of claim 37 wherein the processor further includes coded instructions to control in the absence of a detection of a respiratory cycle of the patient an automatic periodic return of the timing threshold from a more vigilant threshold approximating normal expected respiration timing to a less vigilant threshold deviating from normal expected respiration timing.

54. The apparatus of claim 53 wherein the coded instructions further control a change of the timing threshold to the more vigilant threshold from the less vigilant timing threshold after delivering a machine breath if a subsequent respiratory cycle of the patient remains undetected.

55. The apparatus of claim 53 wherein the coded instructions control the automatic periodic return of the timing threshold as a function of a number of consecutive delivered machine breath

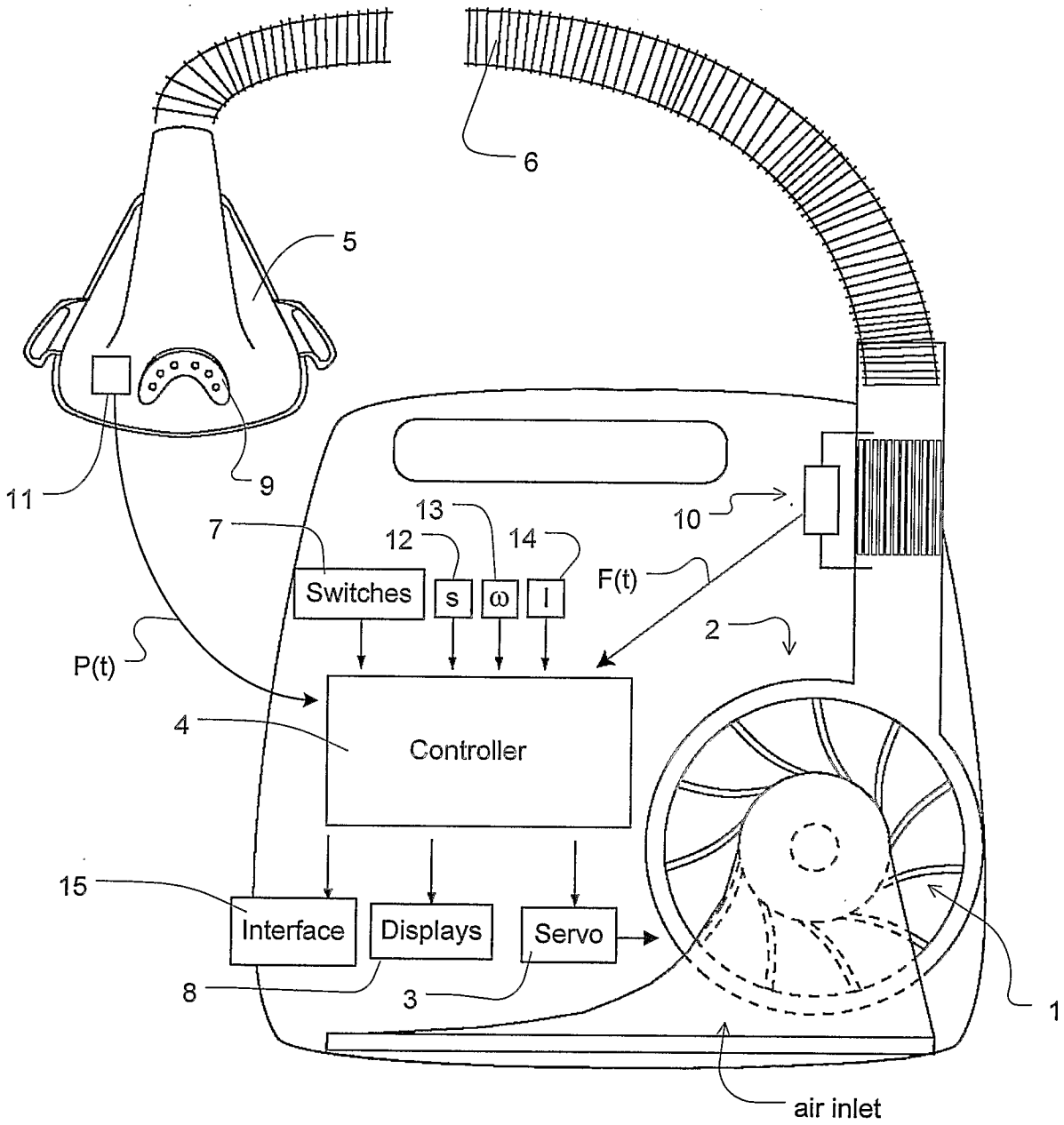

6
5
11
9
7
13
12
14
10
Switches
s
ω
l
F(t)
2
P(t)
4
Controller
15
Interface
Displays
Servo
8
3
1
air inlet

FIG. 1

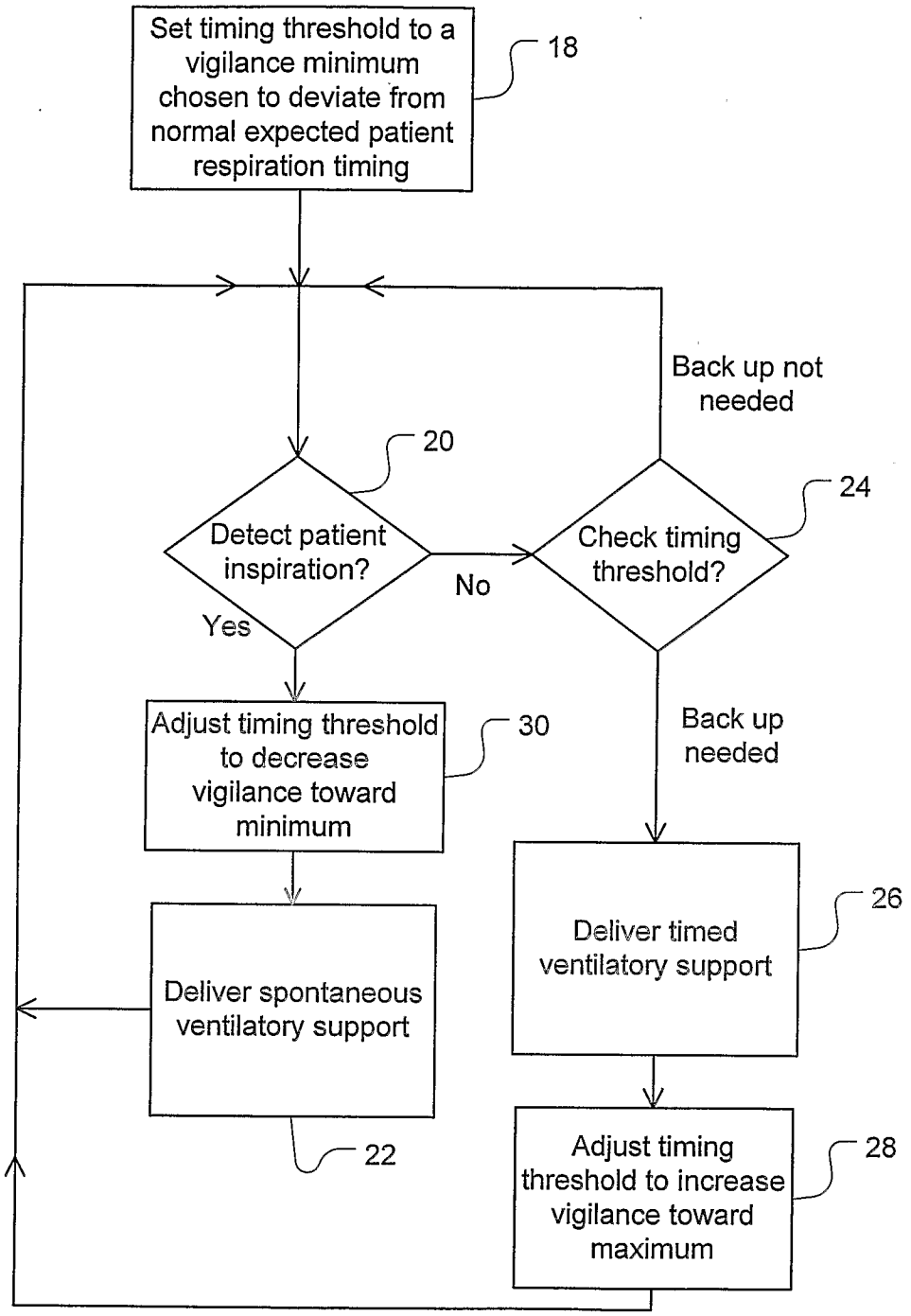

Set timing threshold to a vigilance minimum chosen to deviate from normal expected patient respiration timing
18
Back up not needed
20
Detect patient inspiration?
24
Check timing threshold?
No
Yes
Adjust timing threshold to decrease vigilance toward minimum
30
Back up needed
Deliver timed ventilatory support
26
Deliver spontaneous ventilatory support
22
Adjust timing threshold to increase vigilance toward maximum
28

FIG. 2

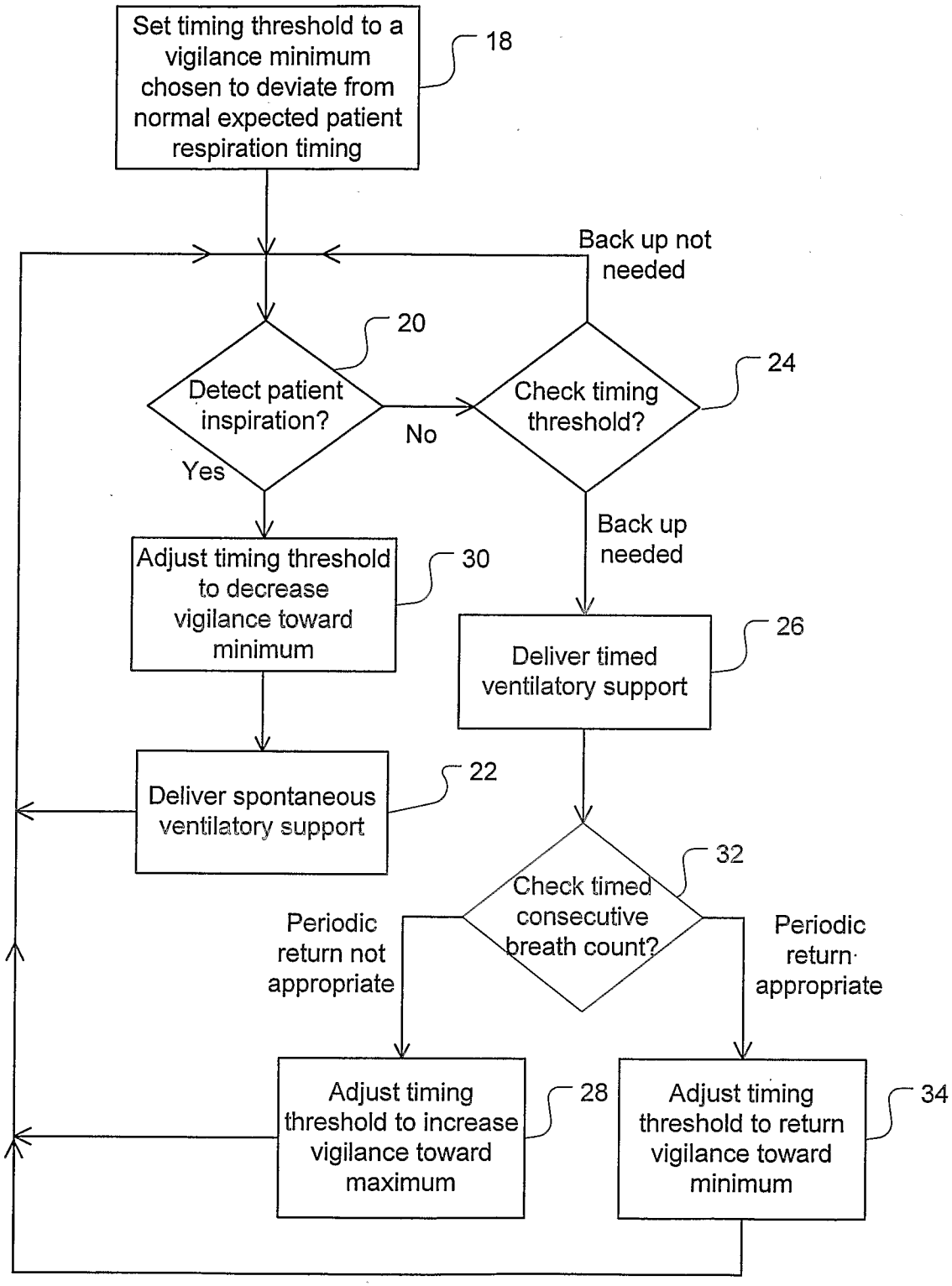

Set timing threshold to a vigilance minimum chosen to deviate from normal expected patient respiration timing
18
Back up not needed
20
Detect patient inspiration?
Yes
No
Check timing threshold?
24
Back up needed
Adjust timing threshold to decrease vigilance toward minimum
30
Deliver timed ventilatory support
26
Deliver spontaneous ventilatory support
22
Check timed consecutive breath count?
32
Periodic return not appropriate
Periodic return appropriate
Adjust timing threshold to increase vigilance toward maximum
28
Adjust timing threshold to return vigilance toward minimum
34

FIG. 3

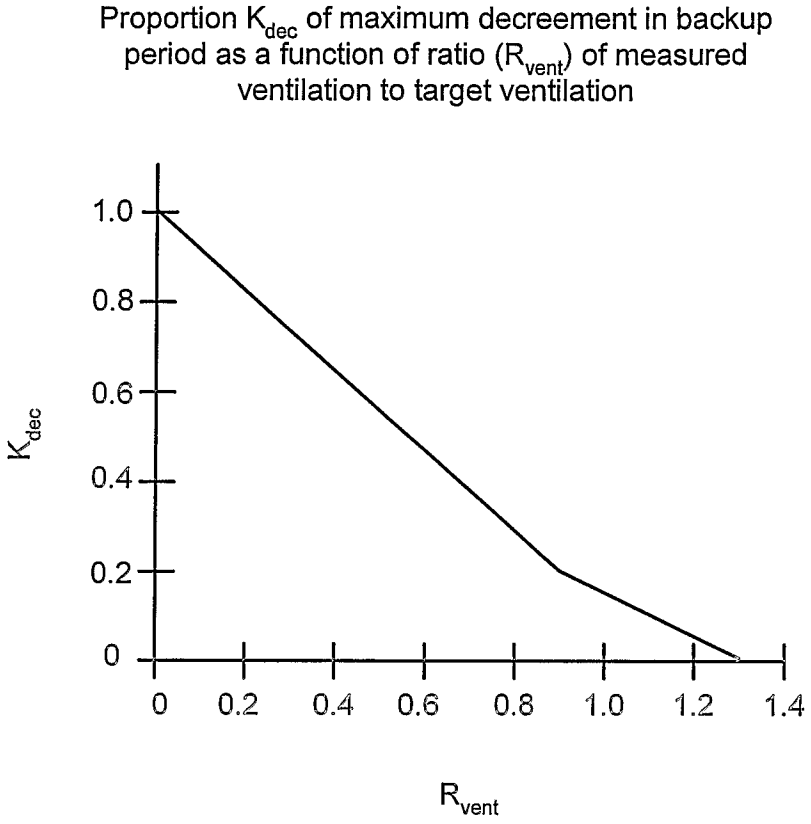

Proportion K_{dec} of maximum decreement in backup period as a function of ratio (R_{vent}) of measured ventilation to target ventilation
1.0
0.8
0.6
0.4
0.2
0
K_{dec}
0
0.2
0.4
0.6
0.8
1.0
1.2
1.4
R_{vent}

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000272

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61M 16/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI - IPC A61M 16/- & keywords: respiration, control, timing, back-up and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,213,119 B1 (BRYDON et al) 10 April 2001 Abstract, figure 11, column 7 lines 13 to 18	
A, P	EP 1 346 743 A1 (GOTLIEB WEINMANN GERAETE FUR MEDIZIN UND ARBEITSSCHUTZ GMBH+ CO) 24 September 2003 Abstract	
A, P	US 6,532,960 B1 (YURKO) 18 March 2003 Abstract	

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
19 April 2004

Date of mailing of the international search report
22 APR 2004

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaustralia.gov.au
Facsimile No. (02) 6285 3929

Authorized officer

ED KNOCK

Telephone No.: (02) 6283 2217

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000272

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	6213119	AU	20339/99	AU	72072/96	CA	2235939
		EP	0858352	WO	9715343		
EP	1346743	DE	10212497				
US	6532960	US	2003127097				

END OF ANNEX